K12-0048

JUN 20 2012

5. 510(k) SUMMARY of Safety and Effectiveness

[21 CFR 807.92]

5.1 Submitter [807.92 (a)(1)]

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5.2 Submission Correspondent [807.92 (a)(1)]

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5.3 Date Summary Prepared [807.92 (a)(1)]

December 29, 2011

5.4 Device Names [807.92 (a)(2)]

Proprietary DRFP propoints (4%, 6%, PT, S) [1]

Model Numbers

4%	0.25-CMX001, 0.30-CMX011, 0.35-CMX012, 0.40-CMX013, 0.45-CMX014
6%	0.25-CMX002, 0.30-CMX021, 0.35-CMX022, 0.40-CMX023, 0.45-CMX024
PT	F1-CMX031, F2-CMX032, F3-CMX033, F4-CMX034, F5-CMX035
S	S2-CMX061, S3-CMX062, S4-CMX063

Common Root Canal Obturation Points

Classification Names Resin, Root Canal Filling

Product Code/ CFR KIF Class II CFR 872.3820

[1] Component of ProSmart Root Canal Obturation System K100248

5.5 Reason for Submission [807.81(3)(i)]

To submit bench & clinical performance data to demonstrate that the previously cleared DRFP propoints (4%, 6%, PT, S – K100248) are safe and effective for the obturation of root canals when used with

Innovative BioCeramix iRoot SP Sealer (K080917)
marketed in the United States by
Brasseler USA Dental L.L.C. as EndoSequence® BC.

5.6 Predicate Device [807.92(a)(3)]

DRFP ProSmart Root Canal Obturation System , **K100248**

propoints (4%, 6%, PT, S) Obturation Points
smartpaste Sealer with Active Powder

5.7 Device Description [807.92(a)(4)]

5.7.1 propoint Obturation Points

The propoints are identical to the points cleared for marketing with K100248. They are made of a radiopaque core and an opaque hydrophilic coating of cross-linked hydrophilic polymers that have been used in the contact lens industry for more than 20 years.

propoints are offered in the traditional 4% and 6% sizes and for use with variable taper files (such as ProTaper™ and Sendoline S5™). They are biocompatible and fully opaque. The hydrophilic coating expands radially to push the sealer into irregularities and voids present in the root canal system for a tight mechanical seal with the dentine. The coating only expands into available space and does not exert pressure on tooth structures. Dimensional length stability is maintained.

The points are packaged in clean room conditions and come individually wrapped to prevent cross-contamination. They can be cut to exact tip size and length.

No heating or compression equipment is required. Post insertion can commence immediately after root canal has been filled. The hydrophilic properties of the device allow extraction without softeners in revision procedures.

propoints are

- coated with DRFP smartpaste prior to insertion into the root canal **(K100248)** or
- inserted after the root canal has been filled with EndoSequence® BC.

To demonstrate the safety and effectiveness of root obturations with this sealer is the subject of this submission.

5.7.2 EndoSequence® BC Sealer

NOTE: Only the interaction with this sealer, not the device itself, is the subject of this submission.

It "is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. EndoSequence® BC (iRoot SP) is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. The sealer does not shrink during setting and demonstrates excellent physical properties." [2]

[2] Quoted from K080917 iRoot SP Summary, Innovative BioCeramix, Inc.

5.8 Statement of Intended Use [807.92(a)(5)]

DRFP propoint obturation points are designed for permanent sealing of root canals when used with DRFP smartpaste dental sealer or with EndoSequence® BC Sealer following established endodontic procedures by qualified healthcare professionals.

Federal US Law restricts propoints (K100248) and Brasseler EndoSequence® BC (K080917) to sale by or on the order of a dentist.

5.9 Comparison with Predicate Devices [807.92(a)(6)]

The use of propoints with Brasseler EndeSequence® BC Sealer for root canal obturations is substantially equivalent to the performance of the **DRFP ProSmart Root Canal Obturation System (K100248).**

	DRFP propoints w/Brasseler EndoSequence ® BC	DRFP ProSmart System K100248
Effectively bonds with dentine and dentine tubules in root canal	Yes	Yes
Meets Bench Test Criteria in Dye Ingress Test	Yes	Yes
Effect of Interaction with Sodium Hypochlorite / EDTA residual levels after rinsing 3 times	None	None
Biocompatible	Yes	Yes
Reported Failure Rate in Clinical Use[3]	0.8%	1.0%
Radiopacity in Clinical X-rays	Good	Good

5.10 Performance Data [807.92(b)]

5.10.1 BenchTests (807.92(b)(1)

DRFP propoints used with EndoSequence® BC Sealer:

1) **In-Vitro Dye Penetration and Sealing Test to Validate Effective Seal**
Heat-sterilized extracted teeth (more brittle and desiccated than patients' teeth), filled with EndoSequence® and propoints and immersed in Brilliant Blue Dye solution for at least one week, showed no sign of dye ingress after sectioning and assessment under a microscope.

[3] Includes immediate tooth failures such as fracturing, canal ossification, teeth requiring extraction

2) **Exposure to Sodium Hypochlorite**
The manufacturer recommends to rinse the canal three (3) times prior to insertion of the endodontic components. If this regime is followed, the remaining value of 0.01% sodium hypochlorite will have no effect on the safety and effectiveness of the devices.

3) **Exposure to EDTA**
Undiluted 17% EDTA has shown to have no effect on the system.

4) **Radiopacity**
Clinical x-rays validate the excellent radiopacity of both devices.

5.10.2 Clinical Performance (807.92(b)(2)
18 months of clinical use demonstrate that propoint and EndoSequence® Sealer form an effective and safe system for the obturation of root canals. Out of approx. 2000 treatments, the DRFP User Panel of practicing dentists reports a 0.8% failure rate that is predominantly attributed to tooth rather than material problems. An abundance of clinical x-rays confirm effective bonding to tooth structures and provide evidence of good healing.

5.10.3 Conclusion (807.92(b)(3)
Bench test results and clinical evidence based on more than 2000 treatments performed by DRFP User Panel of practicing dentists, including x-rays, show that DRFP propoints with Brasseler USA EndoSequence ® BC sealer form an effective system for root canal obturations.

5.11 Contraindications

The manufacturer recommends to not use the system in pregnant women and in nursing mothers.

5.12 Information Bearing on Safety and Effectiveness

[807.92 (b)(3)]

The materials used in DRFP propoints and EndoSequence® BC Sealer have a long history of safe and effective use in dental and other medical devices.

Biocompatibility testing according to ISO 10993 and ISO 7405 has shown the materials to be non-toxic, non-carcinogenic and biocompatible with tissue fluids[4]. There are no characteristics known that should adversely affect the safety and effectiveness of this device combination.

Performance bench test results and abundant clinical data demonstrate that DRFP propoints in combination with Brasseler USA EndoSequence® BC Sealer form an effective and safe system for the obturation of dental root canals and that it is substantially equivalent to the predicate.

The results of design validation and non-clinical and clinical performance testing raise no new issues of safety and effectiveness.

[4] As demonstrated in K080917 (iRoot SP) and K100248

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DRFP, Limited
C/O Ms. Dagmar Maser
Regulatory Consultant, Medical Devices
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NETHERLANDS

JUL 12 2012

Re: K120048
Trade/Device Name: DRFP Propoints 4%, 6%, PT, S[1] Extension of Labeling for use with Brasseler USA EndoSequence® SP[2]
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: June 14, 2012
Received: June 18, 2012

Dear Ms. Maser:

This letter corrects our substantially equivalent letter of June 20, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

INDICATIONS FOR USE

510(k) Number (if known): K120048

Device Name: **DRFP propoints 4%, 6%, PT, S**[1]
Extension of Labeling for Use with
Brasseler USA EndoSequence® SP[2]

INDICATIONS FOR USE:

DRFP **pro**point obturation points are designed for permanent sealing of root canals when used with DRFP **smart**paste Dental Sealer or Brasseler USA EndoSequence® BC Sealer following established endodontic procedures by qualified healthcare professionals.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120048

Concurrence of CDRH, Office of Device Evaluation (ODE)

[1] K100248
[2] US Brand Name for Innovative BioCeramix Inc. iRoot SP, K080917